The Effect of the Severity of Preoperative Leg Pain on Patient Reported Outcomes, Minimum Clinical Important Difference Achievement, and Patient Satisfaction Following Minimally Invasive Transforaminal Lumbar Interbody Fusion

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INTRODUCTION: Prior literature has associated patient satisfaction following surgery to patient perception of progress in specific quality of life domains, notably disability, physical function, and pain. It remains unclear, however, if preoperative severity of pain influences patient satisfaction postoperatively. We aim to compare patient-reported outcomes (PROMs), patient reported satisfaction, and Minimum Clinical Important Difference (MCID) achievement following minimally invasive transforaminal lumbar interbody fusion (MIS TLIF) in patients stratified by preoperative leg pain.

METHODS: A surgical database was retrospectively reviewed for lumbar procedures between November 2005 and March 2021. Inclusion criteria were set as primary, elective, single MIS TLIF procedures for degenerative spinal pathology. Patients undergoing a revision procedure, or surgery indicated for infectious, malignant, or traumatic etiologies were excluded. Patients were grouped into two cohorts, dependent on preoperative VAS leg scores of ≤7 or >7. Patient demographics, perioperative characteristics, PROMs, and patient reported satisfaction scores were collected. PROMs were administered at preoperative and various postoperative time points, including Patient-Reported Outcomes Measurement Information System Physical Function (PROMIS-PF), Visual Analogue Scale (VAS) for back and leg pain, Oswestry Disability Index (ODI), 12-Item Short Form Physical Composite Score and Mental Composite score (SF-12 PCS/SF-12 MCS). Patient satisfaction scores were collected for VAS back and leg pain and ODI at postoperative time points. Mean PROM scores were compared between cohorts at each time point utilizing a two-sample t-test. Postoperative PROM improvement from the preoperative baseline within each cohort was calculated with the use of paired t-test. MCID achievement was determined by comparing ΔPROM scores to previously established threshold values. Rates of MCID achievement were compared among groups via chi square analysis. Postoperative satisfaction scores at each time point were compared between cohorts using a Student's t-test.

RESULTS:

562 patients were eligible with 168 patients in the VAS leg Preoperative ≤7 cohorts. Demographic differences between cohorts were observed for age and smoking status ($p \leq 0.044$, all). A greater proportion of patients in the VAS leg Preoperative ≤7 cohorts had a preoperative diagnosis of foraminal stenosis ($p \leq 0.001$). Postoperative inpatient VAS pain score on day 0 was greater for patients in VAS leg preoperative >7 cohort ($p < 0.038$). Postoperative narcotic consumption on day 0 and 1 was noted to be significantly greater in VAS leg Preoperative >7 cohort. Preoperative PROM scores were different for the following PROMS at the following timepoints: SF-12 MCS, VAS back, and VAS leg ($p < 0.008$, all). Differences in postoperative mean PROMs were demonstrated: PROMIS-PF at 6 weeks and 2 years, SF-12 PCS at 6 weeks and 2 years, SF-12 MCS at 6 weeks, 12 weeks. 6 months, and 1 year, VAS back at 6 weeks, 12 weeks, and 6 months, VAS leg at 6 weeks, 12 weeks, 6 months, and 2 years and ODI at all postoperative time points ($p < 0.045$, all). Patients in the VAS leg Preoperative >7 cohort demonstrated a greater proportion of achieving MCID for VAS leg at all postoperative time points and for ODI at 12 weeks ($p < 0.010$, all). Patients in the VAS leg Preoperative ≤7 cohort demonstrated a greater proportion achieving MCID for PROMIS-PF at 2 years and for SF-12 PCS at 2 years. Postoperative satisfaction was greater in the VAS back preoperative ≤7 cohort for the following PROMs at the following timepoints: VAS leg at 6 weeks, 12 weeks, 6 months, and 2 years, VAS back at 12 weeks and 2 years, and ODI at 6 weeks, 12 weeks, 6 months, and 2 years ($p < 0.046$, all).

DISCUSSION AND CONCLUSION: Patients with severe preoperative leg pain demonstrated significantly worse postoperative PROM scores for the majority of PROMs at most time points and *significantly worse patient satisfaction* for disability, back and leg pain at multiple time points. MCID achievement rates across cohorts were similar for the majority of PROMs at the majority of postoperative time-points. This may suggest patients with severe preoperative pain have unrealistic expectations for benefits of surgery influencing their corresponding satisfaction postoperatively.

Table 1. Patient Demographics

Characteristic	**Total (n=562)**	**VAS leg Pre ≤7 (n=168)**	**VAS leg Pre >7 (n=394)**	***p-value**
Age (mean ± SD, years)	51.9 ± 11.5	53.4 ± 10.6	51.3 ± 11.9	**0.044**
BMI (mean ± SD, kg/m²)	30.6 ± 6.2	30.2 ± 6.03	30.92 ± 6.32	0.134
Gender				0.106
Female	37.2% (209)	32.1% (54)	39.3% (155)	
Male	62.8% (353)	67.9% (114)	60.7% (239)	
Ethnicity				0.120
Caucasian	68.3% (388)	73.8% (124)	67.4% (264)	
African American	12.9% (72)	10.7% (18)	13.8% (54)	
Hispanic	12.7% (71)	8.3% (14)	14.5% (57)	
Asian	1.4% (8)	2.4% (4)	1.0% (4)	
Other	3.8% (21)	4.8% (8)	3.3% (13)	
Diabetic Status				0.796
Non-Diabetic	87.5% (492)	88.1% (148)	87.3% (344)	
Diabetic	12.5% (70)	11.9% (20)	12.7% (50)	
Smoking Status				**<0.001**
Non-Smoker	80.2% (450)	89.2% (149)	76.4% (301)	
Smoker	19.8% (111)	10.8% (18)	23.6% (93)	
Hypertension Status				0.077
Non-hypertensive	61.3% (343)	66.9% (111)	58.9% (232)	
Hypertensive	38.8% (217)	33.1% (55)	41.1% (162)	
ASA Classification				0.694
<2	81.3% (451)	80.3% (130)	81.7% (321)	
>2	18.7% (104)	19.8% (32)	18.3% (72)	
CCI Score (mean ± SD)	2.1 ± 1.9	2.0 ± 1.8	2.2 ± 2.0	0.173
Insurance				0.057
Medicare/Medicaid	9.6% (54)	5.0% (8)	11.7% (46)	
Workers' Compensation	40.5% (228)	34.0% (57)	43.4% (171)	
Private	49.8% (280)	61.3% (103)	44.9% (177)	

Boldface indicates statistical significance
ASA = American Society of Anesthesiologists; CCI = Charlson Comorbidity Index; SD=standard deviation
*p-values calculated using Chi-square analysis and Student's t-test for categorical and continuous variables, respectively

Table 2. Perioperative Characteristics

Characteristic	**Total (n=562)**	**VAS leg Pre ≤7 (n=168)**	**VAS leg Pre >7 (n=394)**	***p-value**
Spinal Pathology				
rHNP	20.1% (113)	25.0% (42)	18.0% (71)	0.059
Degenerative Spond	62.5% (351)	66.1% (111)	60.9% (240)	0.248
Foraminal Stenosis	25.3% (142)	46.4% (78)	16.2% (64)	**<0.001**
Central Stenosis	84.8% (477)	87.5% (147)	83.8% (330)	0.257
Operative Levels				0.576
L1-2	0.2% (1)	0.0% (0)	0.3% (1)	
L2-3	0.7% (4)	0.0% (0)	1.0% (4)	
L3-4	4.3% (24)	4.2% (7)	4.3% (17)	
L4-5	53.9% (303)	57.1% (96)	52.5% (207)	
L5-S1	40.9% (230)	38.7% (65)	41.9% (165)	
Operative Time (Mean ± SD; min)	120.8 ± 35.8	122.5 ± 29.3	120.0 ± 38.2	0.453
Estimated Blood Loss (Mean ± SD; mL)	61.3 ± 57.1	54.1 ± 50.2	63.7 ± 58.9	0.085
Length of Stay (Mean ± SD; hours)	48.4 ± 32.9	31.7 ± 20.7	55.4 ± 34.5	**<0.001**
Postoperative VAS pain				
POD 0	5.2 ± 1.8	4.9 ± 1.9	5.3 ± 1.8	**0.038**
POD 1	4.7 ± 1.6	4.6 ± 1.7	4.7 ± 1.6	0.557
Postoperative Narcotic Consumption				
POD 0	88.1 ± 71.3	55.1 ± 29.7	99.5 ± 77.6	**<0.001**
POD 1	68.7 ± 78.1	41.5 ± 32.8	78.1 ± 86.6	**<0.001**
1-year Arthrodesis (%)	86.3% (429)	84.9% (107)	86.8% (322)	**<0.001**

Boldface indicates statistical significance
rHNP = Recurrent Herniated Nucleus Pulposus; Spond = Spondylolisthesis; POD=Postoperative Day; SD=Standard Deviation
*p-values calculated using Chi-square analysis and Student's t-test for categorical and continuous variables, respectively

Table 3: Mean PROMs and Postoperative Improvement

PROM	**VAS leg Pre <7 Mean ± SD**	**VAS leg <7 Post-operative Improvement**	**VAS leg Pre >7 Mean ± SD**	**VAS leg >7 Postoperative Improvement**	***p-value**
PROMIS-PF					
Preoperative	36.3 ± 5.9 (84)	-	34.2 ± 6.6 (57)	-	0.06
6-weeks	39.9 ± 6.8 (70)	**0.043**	36.1 ± 7.1 (48)	**0.028**	**0.019**
12-weeks	41.1 ± 7.2 (69)	**<0.001**	40.1 ± 6.6 (43)	**<0.001**	0.467
6-months	43.5 ± 7.7 (68)	**<0.001**	43.6 ± 7.2 (42)	**<0.001**	0.943
1-year	44.5 ± 8.6 (50)	**<0.001**	43.7 ± 7.6 (39)	**<0.001**	0.667
2-year	47.0 ± 8.8 (43)	**<0.001**	42.0± 9.8 (27)	0.012	**0.045**
SF-12 PCS					
Preoperative	30.4 ± 7.7 (124)	-	29.4 ± 8.3 (109)	-	0.344
6-weeks	32.0 ± 8.3 (93)	0.311	29.5 ± 8.0 (91)	**0.033**	**0.036**
12-weeks	35.2 ± 9.9 (102)	**<0.001**	32.9 ± 9.5 (73)	**0.004**	0.134
6-months	39.1 ± 11.9 (84)	**<0.001**	37.7 ± 10.9 (77)	**<0.001**	0.443
1-year	40.5 ± 11.6 (66)	**<0.001**	38.5 ± 11.6 (81)	**<0.001**	0.309
2-year	41.8 ± 10.8 (46)	**<0.001**	37.1± 11.9 (38)	**<0.001**	**0.013**
SF-12 MCS					
Preoperative	49.9 ± 11.3 (124)	-	45.9 ± 12.1 (109)	-	**0.008**
6-weeks	52.9 ± 10.9 (94)	**0.005**	49.3 ± 11.6 (94)	**0.002**	**0.030**
12-weeks	54.3 ± 10.9 (102)	**<0.001**	50.2 ± 11.9 (76)	**0.002**	**0.018**
6-months	54.2 ± 9.6 (84)	0.001	50.3 ± 11.8 (78)	**<0.001**	**0.022**
1-year	54.6 ± 9.6 (66)	0.011	50.1 ± 11.5 (81)	**<0.001**	**0.012**
2-year	54.4 ± 11.1 (46)	0.454	51.1 ± 10.8 (38)	0.316	0.179
VAS back					
Preoperative	5.7 ± 2.2 (143)	-	7.0 ± 2.1 (372)	-	**<0.001**
6-weeks	3.4 ± 2.3 (120)	**<0.001**	4.3 ± 2.4 (382)	**<0.001**	**<0.001**
12-weeks	3.4 ± 2.6 (118)	**<0.001**	4.1 ± 2.5 (352)	**<0.001**	**0.016**
6-months	3.2 ± 2.6 (116)	**<0.001**	3.9 ± 2.6 (331)	**<0.001**	**0.022**
1-year	2.9 ± 2.7 (57)	**<0.001**	3.6 ± 2.9 (63)	**<0.001**	0.201
2-year	3.2 ± 2.7 (38)	**<0.001**	4.2 ± 3.0 (36)	**<0.001**	0.130
VAS leg					
Preoperative	4.1 ± 2.3 (144)	-	8.4 ± .97 (110)	-	**<0.001**
6-weeks	2.5 ± 2.6 (120)	**<0.001**	3.9 ± 3.1 (123)	**<0.001**	**<0.001**
12-weeks	2.2 ± 2.5 (117)	**<0.001**	3.8 ± 2.7 (113)	**<0.001**	**<0.001**
6-months	2.3 ± 2.4 (116)	**<0.001**	3.6 ± 2.9 (106)	**<0.001**	**<0.001**
1-year	2.3 ± 2.7 (56)	**<0.001**	3.3 ± 2.9 (62)	**<0.001**	0.059
2-year	2.1 ± 2.6 (38)	**<0.001**	3.6 ± 2.8 (36)	**<0.001**	**0.019**
ODI					
Preoperative	42.9 ± 14.2 (144)	-	50.0 ± 18.0 (114)	-	0.057
6-weeks	33.9 ± 18.1 (121)	**<0.001**	43.2 ± 20.8 (129)	**<0.001**	**<0.001**
12-weeks	29.1 ± 16.5 (118)	**<0.001**	37.5 ± 20.5 (125)	**<0.001**	**<0.001**
6-months	22.2 ± 16.2 (118)	**<0.001**	32.1 ± 20.8 (119)	**<0.001**	**<0.001**
1-year	20.8 ± 19.5 (57)	**<0.001**	32.2 ± 23.9 (90)	**<0.001**	**0.003**
2-year	20.9 ± 20.3 (38)	**<0.001**	29.8 ± 20.5 (35)	**<0.001**	**0.045**

Boldface indicates statistical significance
SD = Standard Deviation
*p-values calculated using unpaired Student's t-test to determine postoperative improvement
†*p-values calculated using two-sample t-test to compare mean PROM scores

Table 4: MCID achievement

PROM	**VAS leg Pre ≤ 7 (%)**	**VAS leg Pre >7 (%)**	***p-value**
ODI			
6-weeks	27.3%	36.0%	0.163
12-weeks	32.2%	53.8%	**0.002**
6-months	55.1%	58.3%	0.646
1-year	54.4%	58.3%	0.685
2-year	50.0%	60.9%	0.409
Overall	60.9%	67.2%	0.297
PROMIS-PF			
6-weeks	12.5%	17.1%	0.514
12-weeks	31.2%	31.4%	0.977
6-months	44.3%	48.5%	0.695
1-year	51.1%	43.3%	0.509
2-year	55.0%	39.1%	**0.023**
Overall	58.9%	54.0%	0.579
SF-12 PCS			
6-weeks	25.9%	31.3%	0.458
12-weeks	51.6%	46.2%	0.528
6-months	58.4%	51.9%	0.465
1-year	66.1%	63.8%	0.807
2-year	75.6%	58.6%	**0.013**
Overall	68.5%	63.1%	0.431
SF-12 MCS			
6-weeks	26.7%	30.0%	0.653
12-weeks	25.8%	34.6%	0.258
6-months	28.6%	40.4%	0.163
1-year	25.4%	40.4%	0.100
2-year	26.8%	27.6%	0.944
Overall	43.1%	51.2%	0.264
VAS back			
6-weeks	52.1%	57.0%	0.351
12-weeks	51.3%	58.5%	0.176
6-months	53.9%	58.1%	0.436
1-year	52.6%	66.7%	0.145
2-year	55.3%	58.6%	0.783
Overall	68.6%	75.8%	0.102
VAS Leg			
6-weeks	37.5%	67.4%	**<0.001**
12-weeks	41.0%	73.3%	**<0.001**
6-months	41.4%	68.3%	**<0.001**
1-year	39.3%	64.6%	**0.010**
2-year	34.2%	82.6%	**<0.001**
Overall	56.5%	83.0%	**<0.001**

Boldface indicates statistical significance
*p-values calculated using chi square analysis

Table 5. Satisfaction Score by VAS Back Preoperative Cut-off

PROM	**VAS leg < 7** (Mean ± SD)	**VAS leg Pre >7** (Mean ± SD)	***p-value**
VAS leg			
6-weeks	7.7 ± 2.9	5.0 ± 3.9	**0.019**
12-weeks	7.6 ± 2.6	5.4 ± 1.0	**0.039**
6-months	7.3 ± 3.2	5.2 ± 4.7	**0.041**
1-year	6.4 ± 3.5	6.9 ± 3.8	0.651
2-years	6.0 ± 4.2	3.2± 4.1	**0.012**
VAS back			
6-weeks	7.3 ± 2.6	5.8 ± 3.4	0.111
12-weeks	7.4 ± 2.1	5.2 ± 3.8	**0.021**
6-months	6.1 ± 3.4	5.4 ± 4.0	0.522
1-year	7.0 ± 3.3	5.9 ± 3.8	0.371
2-years	7.5 ± 2.8	4.1 ± 4.7	**0.033**
ODI			
6-weeks	7.0 ± 2.1	5.0 ±3.2	**0.027**
12-weeks	7.2 ± 1.8	5.4 ± 3.6	**0.033**
6-months	7.0 ± 2.6	4.8 ± 4.0	**0.046**
1-year	7.4 ± 2.4	6.3 ± 3.5	0.258
2-years	7.0 ± 2.9	4.0 ± 3.5	**0.028**

Boldface indicates statistical significance
*p-values calculated using Student's t-test